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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,188	02/12/2004	Peter James Jenkins	08505.0020	3089

22852 7590 05/09/2005

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
PESELEV, ELLI	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 05/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,188	JENKINS ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *30-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

Claims 30-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 30, 2004.

Claims 1-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth in the Office Action of January 26, 2005.

Applicant's arguments filed April 26, 2005 have been considered but have not been found persuasive.

With respect to the treatment if diabetes, note that the data presented on pages 22-23 of the specification is directed to the monitoring blood glucose level with administration of insulin alone or insulin in combination with Gibberellin A3. The specification provides no evidence that Gibberellin alone is effective in lowering blood glucose levels. Therefore, applicant has failed to present any evidence of the effectiveness of the claimed method.

With respect to the term "glycosidic", applicant has submitted a reference showing glycosylation of organic molecules and refers to the Oden Patent for the teaching of a glycoside substituent of a gibberrelin.

With regard to the terms "allyl", aryl, arylalkyl, amidine and unsaturated or saturated ring", applicant contends that variation of the number of carbon atoms in said

terms can be accomplished by numerous documented techniques and that the specification provides clear procedures on how to evaluate such compounds for use in claimed methods.

These arguments have not been found persuasive. With respect to the Oden Patent, note that Oden provides a definition of glycoside in column 4, lines 63-67. Further, the test for enablement is not only how to make the compounds encompassed by the claims but rather how the following factors apply to the claimed invention.

The factors regarding undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);

In the instant case the terms glycosidic", allyl, aryl, arylalkyl, amidine and unsaturated or saturated ring encompass a very large number of substituents having divergent structural formulas. For example, the term "glycosidic" encompasses glucose, lactose, sucrose, starch, cellulose, chitin, hyaluronic acid, dextran, dextrin, guar gum, etc. The term "allyl" encompasses an allyl having 3 carbon atoms and an allyl having 100 atoms and everything in between. The term "aryl" encompasses benzene, naphthalene, anthracene, phenanthrene, benzpyrene, chrysene etc. The terminology "unsaturated or saturated ring" encompass all ring structures in organic chemistry. Therefore, a great quantity of experimentation is necessary to determine which specific substituents encompassed by the instant claims will result in compounds useful for the treatment of diabetes.

(2) The amount of direction or guidance presented;

The specification fails to provide any amount of direction or guidance of how to select specific substituents encompassed by the instant claims.

(3) The presence or absence of working examples;

The only working examples set forth in the specification relate to Gibberellin A3.

(4) The nature of invention;

The nature of the invention is such that it is directed to anti-diabetic agents and their use for the treatment of diabetes.

(5) The state of the prior art

There is no knowledge in the art of the use of various derivatives of Gibberellins for the treatment of diabetes.

(6) The predictability or unpredictability of the art;

It is well known in the pharmaceutical art that even a minor variation in the structural formula of the compound can have a significant impact on its activity. Therefore, there is a good reason to doubt that, for example, a compound substituted by glucose and benzene will have the same activity as compound substituted by cellulose and chrysene,

(7) The breadth of the claims;

The breath of the claims is such that it encompass such a large number of possible substituents, without any limitations on their structural formulas, that it would take an undue amount of experimentation to determine which specific subsituents will result in acompound having the desired activity.

and

(8) The relative skill of those in the art.

A person having ordinary skill in the art at the time the instant invention was made would no be able to predict which substituents will result in a useful compound.

Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "derivatives" renders the claims indefinite for the reasons set forth in the Office Action January 26, 2005.

Applicant's arguments filed April 26, 2005 have been considered but have not been found persuasive.

Applicant contend that the specification on pages 8-9 provides the definition of the term "derivatives". This argument has not been found persuasive. The specification states "Pharmaceutically acceptable derivatives, including lactones, esters, active esters, and salts" i.e. the definition set forth in the specification is not limited to lactones, glycosides, esters, active esters and salts but encompasses any other derivatives of unknown structural formula.

Claims 17-29 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Oden (U.S. Patent No. 5,580,857), the International Patent WO 96/20703, the International Patent No. 94/26240 or the European Patent No. 0024951 B1 for the reasons set forth in the Office Action of January 26, 2005.

Applicant's arguments filed April 26, 2005 have been considered but have not been found persuasive.

Applicant contends that the art of record does not disclose an anti-diabetic agent.

In response to applicant's argument that the claimed agent is anti-diabetic, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

In response to applicant's arguments, the recitation "ant-diabetic" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Further, note that the cited prior art does not require carriers such as glucose or sucrose.

Claims 1-29 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Davis et al (Journal of the American

Medical Association 79:1, 24-26 (January 1989) for the reasons set forth in the Office Action of January 26, 2005.

Applicant's arguments filed April 26, 2005 have been considered but have not been found persuasive.

Applicant contends that Davis does disclose the treatment of diabetes. Said argument has not been found persuasive. The instant claims are directed to the administration of gibberellins to patient in need thereof i.e. to patients having diabetes. Davis also discloses administration of gibberellins to patient having diabetes. Applicant contends that Davis does not report on the degree of diabetes in the mice before or after administration of the composition, nor does Davis teach that the conditions such as disclosed dosage and time period between administration and killing the mice are sufficient to treat diabetes. This argument has not been found persuasive. Davis teaches that "Diabetic animals were used in this study because of their poor wound healing and anti-inflammatory capabilities" (see Abstract). Therefore, it is clear from the disclosure by Davis that wounds and inflammation are complications and conditions associated with diabetes. Davis also teaches that gibberellin is effective in inhibiting inflammation. Thus, Davis clearly teaches the use of gibberelllin for the treatment of conditions associated with diabetes. With respect to the treatment of diabetes, note that the instant claims are not limited to any degree of diabetes, dosage or the time between the administration of the effective compound and the death of the patient. Therefore, the claimed method is not patentably distinct from the method disclosed by

Davis i.e.administration of the same compound to the same patient at the same dosage will inherently produce the same results.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200